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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/675,461

09/30/2003

Franco Maglione

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08/11/2006

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EXAMINER

SHAY, DAVID M

ART UNIT

PAPER NUMBER

3735

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/675,461

Applicant(s)

MAGLIONE

Examiner

david shay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 12, 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5 and 7-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5 and 7-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicant argues that the examiner has not pointed to the specific portions of the references from which the teachings are drawn. The examiner respectfully notes that the provision of the specific location in the references is not required {“*preferably* with reference to relevant column or page numbers...” (MPEP 706.02(j), emphasis added} “*should* clearly articulate which portions of the references...” (MPEP 2144.08, emphasis added)}. It is further respectfully noted that applicant has been able to locate the limitations that the examiner has enumerated in the rejections. Applicant then argues that the findings of the examiner are insufficient, apparently because the examiner’s motivation “is not found in the references but in a desire to combine these references to meet the elements in the present invention.” The examiner must respectfully but vigorously traverse this assertion. The examiner respectfully notes, as explicitly stated by applicant (see the instant response, page 6, fifth full paragraph), Nichols specifically states laser energy can be used. The examiner must respectfully note that one having ordinary skill in the art would readily perceive that in order to provide laser energy at the tip of a catheter, there must be some means by which to convey the radiation to the tip of the catheter. Thus while this is not stated specifically in Nichols, it is still “knowledge generally available to one of ordinary skill in the art” and as such a valid source for a motivation. As Nichols discusses no means whatsoever to convey the laser radiation, one having ordinary skill in the art would be forced to look to the art of subcutaneous laser application, such as Del Giglio, to determine such a means. Thus the combination of Del Giglio and Nichols is entirely proper, the motivation therefor being found within the knowledge generally available to one of ordinary skill in the art, not from applicant’s disclosure. Similarly, with regard to Proebstle et al, neither Nichols nor Del Giglio teach any particular laser or wavelength, thus once again, one having

ordinary skill in the art would be forced to look to the art of endovenous laser treatment to determine the wavelengths appropriate for blocking veins from within. Thus, once again, the motivation for combining Proebstle et al with Nichols and Del Giglio being found within the knowledge generally available to one of ordinary skill in the art, not from applicant's disclosure.

Applicant asserts that "Nichols does not teach a method of treating varicoceles." This is a curious statement in view of the immediately preceding paragraph, wherein applicant specifically states that Nichols teaches the "blockage of a blood vessel in a varicocele procedure", this would appear to the examiner, and, the examiner believes, to one having ordinary skill in the art, to be a method of treating a varicocele, by blocking a blood vessel, using a catheter (a device notorious in the art for insertion into blood vessels) with a surface that can be heated by a laser. All these various elements, the catheter, the heated surface, and even the heating thereof by a laser, are specifically recited by applicant in the instant response. But applicant has pointed to no disclosure or knowledge in the art, which would lead one having ordinary skill to decide, given the disclosure of all the aforementioned structures, along with specific disclosure of performing "a varicocele procedure" contained within the four corners of the Nichols reference, that these structures should be abandoned and other, unnamed structures employed, or that the devices should be employed, but the traditional methods of use thereof should be forsaken for undisclosed methods. The examiner is at a loss how to respond to such an assertion, except to note that Nichols does, in fact teach blocking a blood vessel in a varicocele procedure.

With regard to the particular wavelength, applicant appears to argue that the 980 nm wavelength is critical, noting the disclosure at page 6 of the originally filed disclosure. The

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examiner must respectfully note that this section of the disclosure merely describes the 980 nm wavelength as “preferred” and the claims merely recite a wavelength of “*about* 980 nm” (emphasis added). However, the examiner will construe applicant’s remarks to indicate that applicant feels that the phrase “about 980 nm” does not extend to 940 nm, as argued by the examiner. With regard to the Proebstle et al article, it is noted that the vapor bubble formation and the distribution of thermal energy in blood, touted as the mechanisms of action in the aforementioned disclosure at page 6 of the originally filed disclosure, is also extensively discussed and experimentally confirmed in Proebstle et al (see for example, the conclusion sentence in the abstract). While it is true that Proebstle et al do caution that if the procedure is improperly done that vessel wall perforation could result, this merely underscores the knowledge of one having ordinary skill in the art of the variation of laser parameters to accommodate the specific circumstance (vessel diameter, fiber size, laser wavelength, and laser pulse parameters). This scope of knowledge of person having ordinary skill in the art is further underscored by the various examples for various blood vessel sizes discussed by Del Giglio.

With regard to the combination including Farley et al, applicant argues “the use of the 980 nm laser has provided superior results in these areas, since prior uses were dedicated to the use of the 980 nm laser for cutting and coagulating tissues in surgery.” The examiner must respectfully note that at least Proebstle et al were aware of the ability of the 980 nm wavelength to treat vessels without perforation. The remainder of applicant’s arguments with respect to Farley et al appear to be directed to showing that Farley et al concentrate on the use of RF energy and only mention lasers briefly and without much detail. While the examiner notes that the claiming of the use of a laser merely serves to further underscore the ability of the person having

ordinary skill in the art to determine the parameters pulse width, energy, etc for the treatment of various size vessels, since absent this knowledge, claim 5 of Farley et al would not be enabled. Since Farley et al is an issued US Patent, applicants arguments standing alone do not provide sufficient evidence to overcome the presumption of validity ascribed thereto. In any event, applicant does not address the teachings of Farley et al employed by the examiner in the rejection of claims 9 to 11 and as such these arguments are not convincing.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5, 7, 8, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nichols in combination with Del Giglio and Proebstle et al. Nichols teaches a method of treating varicoceles by threading a catheter through the venous system and heating material in the vicinity of the end of the device, which can be done by laser radiation. Del Giglio teaches precise placement of an optical fiber, which can be about 400 microns in diameter with a bare tip that is extended 1 cm beyond the tip of the introducer, and applying laser pulses. It would have been obvious to the artisan or ordinary skill to employ the ablation method of Del Giglio in the method of Nichols, since Nichols gives no particulars of the laser application or to employ the varicocele destruction method of Nichols in the method of Del Giglio, since these structures also can be efficaciously treated by laser application, and in either case to employ a 980 nm diode laser, as taught by Proebstle et al, since neither Nichols nor Del Giglio teach any particular laser or wavelength; to employ echo color Doppler ultrasound for visualization, since this particular type of ultrasound provides no unexpected result over the ultrasound suggested by Farley et al; and to perform angiography after the laser has been applied to assure closure of the vessel, since

this is commonly done in angioplastic procedures, official notice of which is hereby taken, thus producing a method such as claimed.

Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nichols in combination with Del Giglio and Proebstle et al as applied to claims 1-5, 7, 8 and 12 above, and further in combination with Farley et al. Farley et al teach a method of treating venous varicosities by threading a catheter through the venous system and confirming the position thereof with ultrasound, fluoroscopy, or angioscopy. It would have been obvious to the artisan of ordinary skill to employ the positioning technique of Farley et al in the combined method of Nichols, Del Giglio, and Proebstle et al, since this would allow treatment of sites not close to the surface of the skin, and to employ echo color Doppler ultrasound for visualization, since this particular type of ultrasound provides no unexpected result over the ultrasound suggested by Farley et al; and to perform angiography after the laser has been applied to assure closure of the vessel, since this is commonly done in angioplastic procedures, official notice of which has already been taken, thus producing a device such as claimed.

Applicant's arguments filed May 12, 2006 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on Monday, Tuesday, Wednesday, Thursday, and Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID M. SHAY
PRIMARY EXAMINER
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